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APPLICATION NO.	FILING DATE	JIANG	FIRST NAMED INVENTOR	P	ATTORNEY DOCKET NO.
09/077,606	07/30/99				MV

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ART UNIT PAPER NUMBER

10/27/99

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. <b>09/077,606</b>	Applicant(s) <b>Jiang, et al.</b>
Examiner <b>Mary B. Tung</b>	Group Art Unit <b>1644</b>

Responsive to communication(s) filed on Sep 3, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 1-38 is/are pending in the application.

Of the above, claim(s) 1-11, 23, 24, and 33-38 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 12-22 and 25-32 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

***DETAILED ACTION***

***Election/Restriction***

1. Applicant's election with traverse of Group II, claims 12-22 and 25-32 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that "Under PCT Rule 13.2, "the requirement of unity of invention...shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." Additionally, the Applicants argue that Groups I-IV are all technically related to polypeptides having lectinic properties and that the Examiner "gives no reasons as to why "unique products" having different "structures and physicochemical properties" and "an additional recited use of the SCL's" prevent the inventions of Groups I-IV from having a "technical relationship... involving one or more of the same or corresponding special technical features." The Applicants also argue that the Examiner has improperly applied US restriction practice to a US national stage PCT application. However, contrary to the assertions of the Applicants, the Examiner explained that "the method of Group IV, drawn to selecting inhibitors of the lectinic activity of SCLs is distinct from SCL peptides of Group II, in that it constitutes an additional recited use of the SCLs; the first use being that implied as a therapy in claims 31 and 32 of Group II." According to 37 C.F.R. 1.475(b) and (c), "a national stage application containing claims to different categories of invention if the claims are drawn to only one of several categories. The instant product claims of Groups I-IV are different products that can be made by different processes and used in different ways, as discussed, *supra*. Therefore, the inventions lack unity under 37 C.F.R. 1.475.

2. The requirement is still deemed proper and is therefore made FINAL.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

***Information Disclosure Statement***

4. The information disclosure statement filed 7/30/98 fails to comply with 37 C.F.R. 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The abstract references by the Patent Abstracts of Japan (Glass) were not available in the parent file and was not supplied, therefore, it was not considered. The calculated sequence alignments were supplied, but there were no abstracts present.

*Specification*

**Arrangement of the Specification**

5. The following order or arrangement is preferred in framing the specification and, except for the title of the invention, each of the lettered items should be preceded by the headings indicated below.

- (a) Title of the Invention.
- (b) Cross-References to Related Applications (if any).
- (c) Statement as to rights to inventions made under Federally-sponsored research and development (if any).
- (d) Background of the invention.
  - 1. Field of the Invention.
  - 2. Description of the Related Art including information disclosed under 37 C.F.R. §§ 1.97-1.99.
- (e) Summary of the Invention.
- (f) Brief Description of the Drawing.
- (g) Description of the Preferred Embodiment(s).
- (h) Claim(s).
- (i) Abstract of the Disclosure.

6. The use of the trademarks such as "PRONASE," page 1, line 20, "SEPHACRYL," page 8, line 16, "TRISACRYL," page 8, line 18, and so on, of the specification has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

7. Each letter of the trademarks must be capitalized. *See MPEP 608.01(V) and Appendix I.*

*Claim Objections*

8. Claim 31 objected to because of the following informalities: "characterised" is misspelled. Appropriate correction is required.

*Claim Rejections - 35 U.S.C. § 112*

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 12, 16-22, 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for polypeptide of SEQ ID NOS:3-6, does not reasonably provide enablement for all "fragments," "modifications" or "derivatives" of such polynucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, unpredictability in the art, the amount of experimentation required, and the amount of direction or guidance presented.
11. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation. Besides the polypeptide of SEQ ID NOS:3-6, the specification fails to provide guidance as to how to determine the amino acid residues which will retain functional modifications (as recited in claim 12) fragments, and derivatives (as recited in claim 16) of the claimed sarcolectin polypeptide. While claim 12 discloses the modification as being one or more amino acid modifications, so long as said modification does not adversely affect the lectinic properties of the sarcolectin, there is insufficient disclosure of actual modifications, fragments or derivatives of SEQ ID NOS:3-6. Despite knowledge in the art for producing polypeptide modifications, fragments and derivatives, the specification fails to provide guidance regarding what deletions from or alterations in the disclosed sequences result in polypeptide modifications, fragments and derivatives that retain a similar sarcolectin activity. Detailed information regarding the structural and functional requirements of the sarcolectin polypeptide is lacking. Therefore, predicting which amino acid modifications, fragments and derivatives would maintain function is well outside the realm of routine experimentation; thus a skilled artisan would require guidance, such as information regarding the location, size, and sequence of deletions and alterations which preserve the lectinic activity, in order to make and use the polypeptides in a manner reasonably commensurate with the scope of the claims.
12. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention.
13. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

14. Claims 12, 13, 15--22 and 25-32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.
15. Claims 12 and 15 are incomplete because it depends upon claim 1, which was not elected.
16. In claim 12, the use of "if necessary" is indefinite. It is unclear which specific limitations the Applicant intend to claim.
17. Claim 13 is indefinite in the use of the phrase "have an amino acid chain in SEQ ID NO: 3". It is unclear if Applicants intend to claim the sequence itself or a part of the sequence. It is suggested that the Applicants use more traditional transitional language such as "comprising" or "consisting".
18. Claim 17 recites the limitation "the SEQ ID NO: 5 peptides". There is insufficient antecedent basis for this limitation in the claim. To overcome this rejection, it is suggested that the Applicants change the wording to eliminate the word "the".
19. Claims 17-20 are indefinite in the use of the word "peptides". Since SEQ ID NO: 5 in claim 17, or SEQ ID NO: 1 of claims 18 and 20, or SEQ ID NO: 6 of claim 19, is a single polypeptide, the claim is indefinite in the use of the plural noun.
20. Claims 18 and 20 are indefinite in the use of the phrase "their own antibodies". It is unclear to which antibodies the Applicants are referring.
21. Claim 19 recites the limitation "the SEQ ID NO: 6 peptides". There is insufficient antecedent basis for this limitation in the claim. To overcome this rejection, it is suggested that the Applicants change the wording to eliminate the word "the".
22. Claim 21 is indefinite in the use of the phrase "on the basis of tissue extracts". It is unclear what manipulation of tissue extracts is intended by the Applicants in the claimed purification process.
23. Claims 21, 25 and 26 contain the trademark/trade names SEPHACRYL S-200 and CM-TRISACRYL-M. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A

trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the chromatography solid phase materials and, accordingly, the identification/description is indefinite.

24. Claim 22 recites the limitation "the fraction". There is insufficient antecedent basis for this limitation in the claim. To overcome this rejection, it is suggested that the Applicants change the wording to eliminate the word "the".
25. In claim 25, the use of the phrase "if desired" is indefinite. It is unclear if the Applicants intend to claim the HPLC step as a necessary step of the recited process.

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26. Claim 27 is indefinite in the recitation of "on which is fixed the sugar and at least two buffers". It is unclear whether Applicants intend to claim a limitation of fixing two buffers to a column.
27. Claim 28 is indefinite in the use of the word "system". It is not clear what components comprise the system and thus the metes and bounds of the claim is unclear.
28. Claim 30 is indefinite in the recitation of step 2, which appears to be a duplicate of step 1.
29. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 32 recites the broad recitation "Therapeutic agents for stimulating the immune system", and the claim also recites "Therapeutic agents for stimulating the immune system, particularly of specific immunity" which is the narrower statement of the range/limitation. Also, claim 32 recites the broad recitation "specific growth factors", and the claim also recites "such as Interleukin 2" which is the narrower statement of the range/limitation.

***Claim Rejections - 35 U.S.C. § 102***

30. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

31. Claims 12, 16, 21, 22, 25-27 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Zeng, et al. (*Biol. Chem. Hoppe-Seyler*, 375:393-399).

32. Zeng teaches a lectin, sarcolectin, identified as a human albumin, which contain at least a part of an amino acid sequence of the recited sequence (see the abstract and Fig. 3) as recited in claim 12, that retain MIF binding lectinic activity (see the abstract) as recited in claim 16, in a process wherein the compounds were extracted from tissue (human placenta, see page 398, col. 1, paragraph 3) using Sephadryl S-200 and DEAE cellulose, using N-acetylneurameric acid as a ligand (see page 398, col. 1, paragraph 3), as recited in claim 25, wherein the stage of affinity chromatography comprises the use of an agarose gel column on which is fixed a sugar (Sephadose 4B comprises agarose and the sugar dextran) and the use of at least 2 buffers (PBS and glycine/HCL, see page 398, col. 2, paragraph 1), and lowering the pH to 5, as recited in claim 30 (see page 397, col. 1, paragraph 1). The sarcolectin taught by Zeng is the same as the disclosed sarcolectin despite the absence of the teaching of CM-Trisacryl-M, as recited in claims 21 and 22 since a product is a product regardless of its method of manufacture, unless the method of manufacture materially alters the product. Claims 21, 25 and 26 are included because the CM-Trisacryl-M column is identified by the Applicants as being an ion exchange column, such as DEAE-cellulose (see page 8, lines 17 and 18), and thus, the step is inherent in the use of DEAE-cellulose by Zeng, et al., unless evidence is provided the step would produce an inherently distinct product than that taught by Zeng, et al. Claim 31 is included because a product, is a product regardless of its intended use. Claim 32 is included because the step of inclusion of the specific growth factor Interleukin 2 is not a required recitation. Additionally, the sarcolectin in PBS would constitute an agent suitable for therapeutic use, as recited in claim 32. Therefore, the reference teaching anticipates the claimed invention.

33. Claims 12-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Glass and Fuchs (*J. Cell Biol.* 101:2366-2373, 1985).

34. Glass and Fuchs teach a 469 amino acid polypeptide encoded by SEQ ID NO: 1, with 98.5% identity over its entire length with SEQ ID NO: 3 of the instant application, 97.0% identity with residues no. 2-135 of SEQ ID NO: 4 of the instant application,

and 100 % identity with SEQ ID NO: 5 of the instant application (see Figure 6, GenBank Accession No. P08729 and B24177). The keratin taught by Glass and Fuchs is the same as the disclosed sarcolectin despite the absence of the teaching of the process for separation, as recited in claims 21 and 22 since a product is a product regardless of its method of manufacture, unless the method of manufacture materially alters the product. Therefore, the reference teaching anticipates the claimed invention.

35. Claims 12-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Glass and Fuchs (*J. Cell Biol.* 107:1337-1350).
36. Glass and Fuchs teach a 469 amino acid polypeptide encoded by SEQ ID NO: 1, with 97.6% identity over its entire length with SEQ ID NO: 3 of the instant application, 94.0% identity with residues no. 2-135 of SEQ ID NO: 4 of the instant application, and 100 % identity with SEQ ID NO: 5 of the instant application (see Figure 6, GenBank Accession No. B24177). The keratin taught by Glass and Fuchs is the same as the disclosed sarcolectin despite the absence of the teaching of the process for separation, as recited in claims 21 and 22 since a product is a product regardless of its method of manufacture, unless the method of manufacture materially alters the product. Therefore, the reference teaching anticipates the claimed invention.
- Conclusion***
37. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.
38. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.
39. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Tuesday through Friday from 8:30 am to 6:00 pm, and on alternating Mondays. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any

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inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

*Mary B Tung*  
October 23, 1999  
Mary B. Tung, Ph.D.  
Patent Examiner  
Group 1640

*David A. Saunders*  
DAVID SAUNDERS  
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